

## REMARKS

In the Office action issued on June 1, 2006, the Examiner acknowledged the filing of a Request for Continued Examination, withdrew the finality of the previous Office action, and entered the Submission filed with the Request for Continued Examination (the Reply and Amendment under 37 C.F.R. §1.116 filed on February 3, 2006).

The Examiner rejected all pending claims (50 through 63) based on art. Specifically, the Examiner rejected Claims 62 and 63 under 35 U.S.C. 102(e) as being anticipated by United States Patent No. 6,287,518 to Ignacio ("Ignacio"). The Examiner rejected Claim 50 under 35 U.S.C. §103(a) as being unpatentably obvious over Ignacio in view of United States Patent No. 6,020,405 to Matzinger *et al.* ("Matzinger"). The Examiner rejected claims 51, 52, 60, and 61 under 35 U.S.C. §103(a) as being unpatentably obvious over United States Patent No. 5,087,659 to Fujisawa ("Fujisawa") in view of United States Patent No. 6,117,685 to Omatsu *et al.* ("Omatsu"). The Examiner rejected Claim 53 under 35 U.S.C. §103(a) as being unpatentably obvious over Fujisawa and Omatsu in further view of United States Patent No. 6,096,533 to Tautvydas ("Tautvydas"). Lastly, the Examiner rejected Claims 54 through 59 under 35 U.S.C. §103(a) as being unpatentably obvious over Fujisawa and Omatsu in further view of Matzinger.

The Applicant has fully considered the Office action and cited references and submits this Reply and Amendment in response to the Examiner's rejections. Reconsideration of the application for patent is requested.

### **Rejections for Claims 51 through 61**

The Applicant has herein canceled Claims 51 through 61. All rejections of these claims are rendered moot and are, therefore, not discussed in detail herein.

### **Rejection of Claim 50**

The Examiner rejected Claim 50 as being unpatentably obvious in view of the combination of Ignacio and Matzinger. The Examiner states that:

"Ignacio et al differ from the instant invention in that there is no disclosure of the a [sic] zinc compound or polyaziridine in the ink sterilization monitoring composition." (June 1, 2006 Office action, page 5, top).

To cure this defect of Ignacio, the Examiner points to Matzinger, indicating that:

"Matzinger et al is directed to ink compositions containing crosslinked cellulosic polymers...and a pigment or dye. The crosslinking takes place by associating the polymers with a crosslinking agent such a [sic] zinc compound – zinc palmitate or zinc stearate...Matzinger et al teach that cellulosic polymers that are crosslinked with organo-metallic compounds provide ink formulations that are good or better in color, adhesion and tack, as well as significant improvements in dye dispersions and stability." (*Id.*) (citations omitted)

Based solely on this characterization of Matzinger, the Examiner summarily concludes that:

"[i]t would have been obvious to one of ordinary skill in the art to use a crosslinked cellulosic binder resin as the polymer in Ignacio et al to provide ink compositions that have superior dye dispersion and stability." (*Id.*)

The Applicant respectfully asserts that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claim 50.

A *prima facie* case of obviousness requires three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. Second, there must be a reasonable expectation of success. Lastly, the references must teach or suggest all limitations of the claims. (See M.P.E.P. §2143).

The Examiner has failed to establish a *prima facie* case of obviousness at least because 1) she has not demonstrated the existence of a suggestion or motivation to combine the Ignacio and Matzinger references, and 2) she has not demonstrated that a skilled artisan would have had a reasonable expectation of success in making the proposed combination. Applicant respectfully asserts that neither a suggestion/motivation to combine nor a reasonable expectation of success actually exists, and, therefore, that a case a *prima facie* obviousness cannot be established.

#### Absence of a suggestion or motivation to combine the references

It is insufficient for an Examiner to summarily conclude that a combination 'would have been obvious to one of ordinary skill in the art' simply because the combination *could* have been made. (M.P.E.P. §2143.01(III)). Rather, the

Examiner must show that the references expressly or impliedly suggest the claimed invention, "...or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." (M.P.E.P. §2142, citing *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)).

Here, in describing the alleged suggestion or motivation to combine, the Examiner has done neither. The Examiner has not pointed to anything in either reference that suggests the desirability of the combination. Rather, the Examiner simply states that the combination would have been obvious "...to provide ink compositions that have superior dye dispersion and stability." (June 1, 2006 Office action, page 5, top)

Thus, the Examiner has not met her burden and the Applicant has no obligation to produce evidence of nonobviousness.

Furthermore, for at least the following reasons, Applicant respectfully asserts that no suggestion or motivation to combine the cited references exists, either in the references themselves, in the nature of the problem to be solved, or in the knowledge generally available to one of ordinary skill in the art.

First, a skilled artisan simply would not be motivated to combine the references because they are directed to different subject matter. While Ignacio is directed to sterilization indicators, Matzinger is directed to ink jet inks. The Matzinger inks include simple colorants (dyes) dispersed in a polymer; they do not include indicators that are activated to change color upon exposure to a particular chemical or atmosphere. In short, Matzinger bears no relation to sterilization indicators.

Because of this diversity of subject matter, a skilled artisan, looking to improve the sterilization indicators taught by Ignacio, simply would not have been motivated to look to Matzinger for such improvements.

Second, a skilled artisan would not be motivated to modify Ignacio with the teachings of Matzinger because Ignacio teaches that the purpose of the binder is to "bind the composition to the substrate." (Ignacio, c. 3, line 40). Ignacio does not describe the binder for the purpose of "dye dispersion and stability" and, therefore, a skilled artisan would not look to Matzinger to modify the polymer or binder in order to improve these parameters.

Lastly, at the time of the invention and with the teachings of Ignacio in hand, a skilled artisan would not have been motivated to combine Ignacio and Matzinger when considering the nature of the problem that was addressed by the Applicant when he invented the subject matter defined by Claim 50. As described in the specification of the pending application:

"[t]he device may additionally comprise an additive to control the

diffusion of plasma gases, such a [sic] crosslinking agent or a plasticizer. These may include zinc compounds or polyaziridines.” (p. 3, lines 10-12).

Ignacio acknowledges that the binder may affect sterilant diffusion. In addressing this issue, though, Ignacio does not suggest or motivate a combination with Matzinger. Indeed, Ignacio doesn't suggest the use of any sort of crosslinking agent. Rather, Ignacio specifically teaches a completely different approach to addressing the issue, stating that:

“The binder resin also may influence the rate at which peracid penetrates into the composition during the sterilization process. The rate of peracid penetration, in turn, may influence the rate of color change of the composition. The monitor composition may contain, for example, between 20% and 98%, or between 40% and 70%, of the resin binder by weight.” (Ignacio, c.3, lines 47 through 53) (emphasis added).

Thus, with Ignacio in hand and in consideration of the Applicant's stated problem of controlling the diffusion of plasma gases, a skilled artisan would have varied the weight percentage of polymer or binder in the monitor composition. The artisan would not have been motivated to combine the reference with the teachings of Matzinger to produce the invention represented by Claim 50.

#### Absence of a reasonable expectation of success

The Examiner has not asserted any reasoning that a reasonable expectation of success exists for the proposed combination. Applicant respectfully asserts that, even if a suggestion or motivation to combine the Ignacio and Matzinger references existed, a skilled artisan would not have had a reasonable expectation of success in making the combination. As a result, a *prima facie* case of obviousness simply cannot be established.

Matzinger is directed to ink jets inks that include colorants dispersed in a reversibly cross-linked polymer. The inks are useful in thermal printers and printing processes in which “...recording is done by thermally melting the ink....” (Matzinger, c.3, lines 21-22). The reference does not contemplate, discuss, or suggest the use of indicator and activator systems. That is, the colorants of the Matzinger inks are always in the color that will ultimately be recorded on a surface when the ink is melted onto the surface.

In contrast, the invention defined by Claim 50 relates to a sterilization

indicator that includes an indicator and activator system. The indicator undergoes a color change only when contacted with a reaction product of the activator and plasma. Thus, the indicator is only in the final color when certain conditions are present.

Matzinger teaches that simple colorant systems, *i.e.*, colorants that don't require activation to adopt a desired color, can have superior dye dispersion and stability when a cross-linking agent is employed. Matzinger neither teaches nor suggests the use of a cross-linking agent with a colorant system that requires activation, such as the system defined by Claim 50.

A skilled artisan would not have had a reasonable expectation of success in modifying Ignacio to include a cross-linking agent, such as that taught by Matzinger, because it is not clear that the binary indicator/activator system would function satisfactorily in a cross-linked polymer. Upon reaction between the activator and plasma, a reaction product is produced that must be able to interact with the indicator to produce the desired color change. It is not clear that this interaction, which may require movement of the reaction product through the polymer to the indicator, would succeed in the presence of a crosslinking agent.

Thus, a skilled artisan would not have had a reasonable expectation of success in the combination of references asserted by the Examiner

For at least these reasons, the Examiner has failed to establish a *prima facie* case of obviousness in her rejection of Claim 50. Applicants respectfully assert that no suggestion or motivation to combine the cited references exists, and that Claim 50 defines patentable subject matter.

### **Rejection of Claims 62 and 63**

The Examiner rejected Claims 62 and 63 as being anticipated by Ignacio. Applicant has herein amended independent Claim 62, from which Claim 63 depends, to require that the indicator device include "a zinc compound or a polyaziridine to control the diffusion of plasma gasses."

In the Office action, the Examiner acknowledged that Ignacio fails to teach this limitation. (See June 1, 2006 Office action, p. 5, top). Accordingly, Ignacio fails to teach every limitation of Claims 62 and 63 and cannot, therefore, qualify as an anticipatory reference under 35 U.S.C. §102. The Applicant respectfully requests withdrawal of this rejection.

### **New Claims 64 through 72**

The Applicant has herein added new Claims 64 through 72. These claims represent, in substantial form, some of Claims 51 through 61, which have been canceled by this Reply and Amendment. The new claims depend from independent Claim 50, wherein the canceled claims depended from independent Claim 51, which also is canceled herein.

All of these new claims are fully supported by the application as filed (see, for example, the discussion appearing at the top of page 15 through the middle of page 16; the discussion appearing at the bottom of page 17 through the top of page 18; and the discussion at the bottom of page 3). No new matter has been introduced.

## **CONCLUSION**

The Applicant has fully responded to the rejections listed by the Examiner in the June 1, 2006 Office Action. As described in detail above, all pending claims, as amended herein, define patentable subject matter. Accordingly, a Notice of Allowability relating to all claims currently under consideration is appropriate and respectfully requested by the Applicant.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

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